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PRINCIPAL INVESTIGATOR: Dr. Gregory Gahm, PhD

CONTRACTING ORGANIZATION: The Geneva Foundation

Tacoma, WA 98402

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14. ABSTRACT This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. During the first year, the study team developed the infrastructure to implement the trial including personnel hiring and training, process development to identify, screen, and enroll participants, completion of study-related VR Iraq scenarios, and research protocol development. During the second year, recruitment and enrollment of soldiers for study participation began, and by the end of year two 145 referrals for treatment had been received, 84 subjects consented to study participation and 45 met all of the inclusion and none of the exclusion criteria and were randomized to treatment. During the third year, recruitment and enrolment of participants continued with an additional 100 referrals for treatment received, 72 subjects consented to study participation and 39 randomized to one of the 3 arms of the study, VR, PE or WL. During year 4, 119 additional referrals were received, 72 participants consented to study participation and 43 were randomized. During year 5, the period covered in this report, 121 referrals have been received, 68 participants consented to study participation and 35 met all the inclusion criteria and none of the exclusion criteria and were randomized.						
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INTRODUCTION.

This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. The study will test the general hypotheses that 10 sessions of VRET will successfully treat PTSD, therapeutically affect levels of physiological arousal, and significantly reduce perceptions of stigma toward seeking behavioral health services. Soldiers returning from deployments to Iraq who are diagnosed with combat-related PTSD following administration of the Clinician-Administered PTSD Scale (CAPS) will be randomized to one of three groups: 1) PE; 2) VRET; or 3) WL. Soldiers will undergo clinical assessments at baseline and after 5 and 10 treatment sessions. Outcome measures will also be collected at 12 and 26 weeks post-treatment. Physiological arousal, patient satisfaction with treatment, and stigma toward seeking behavioral health services will also be explored.

BODY.

During this reporting period the study team continued recruitment, enrollment and follow-up of study participants, ending enrollment of new participants in March 2013 and completion of study related treatment sessions in May 2013. Follow-up assessments for subjects randomized to VR or PE treatment groups will continue. The consultant team provides ongoing treatment fidelity evaluations and the research team is conducting continuous inter-rater reliability assessments.

Initial recruitment for this study began in May 2009. During the current reporting period 121 referrals for treatment were received, 68 subjects consented to study participation and 35 of those met all of the inclusion and none of the exclusion criteria and were randomized to treatment. Total study numbers to date include 485 referrals, 296 subjects consented to study participation and 162 met all of the inclusion and none of the exclusion criteria and randomized to treatment. Of the 54 subjects randomized to the 'waitlist' (WL) condition, 47 subjects have completed study participation through the post-assessment visit, and 7 dropped from study participation, either by withdrawing consent or becoming lost to follow-up. Two are currently active in the WL group. Of the 108 subjects randomized to either active treatment group, 10 are waiting for 12 or 26 week follow-up assessments. 34 subjects have completed study participation through 26 week follow-up. 64 subjects have dropped from study participation prior to completing the 26 week follow-up, either by withdrawing consent or becoming lost to follow-up. Of these 64 drop outs, 17 completed the active treatment phase and post-treatment assessment, 42 subjects withdrew prior to completing 10 treatment sessions/post-assessment, and 5 subjects were withdrawn by the study team during the active phase of the study. Contemporary intent-to-treat analyses will be used, taking advantage of all study participants who provided at least one assessment data point (ie – all participants), thus mitigating the impact of attrition on the scientific value of the study.

Ongoing recording and review of sessions has been implemented in order to ensure treatment fidelity of 15% of treatment sessions.

Modification

Modifications to the protocol were made to add and remove study staff throughout year 5.

An amendment to contact dropped/withdrawn participants by phone and collect a self-report measure (PCL-C) was approved in February 2013. This allows for an additional data point on otherwise dropped participants to be collected. Additional measures for the Ft. Bragg recruitment site (grant W81XWH-11-2-0007) were added to collect data on homework compliance, treatment preference and coping strategies.

Challenges

With the end of grant funding projected for 31MAY2013, a no-cost extension was submitted to USAMRMC in July 2012. Without timely approval of this extension, two key personnel (ie - the research coordinator and primary assessing clinician) accepted offers for other positions. Without confirmation of another extension year on the project, the receipt of new referrals was stopped in February 2012 and the last subject was enrolled in March 2012 to ensure grant-funded time to complete the treatment portion of the study.

Retention of subjects remains a problem due to the operational tempo and highly mobile nature of the active duty population. Of the 71 subjects that withdrew from the study, 27 were noted as withdrawing due to military related move or military training demands. With the protocol modification to complete a phone follow-up with dropped participants, some additional data is able to be collected on the 71 withdrawn subjects.

Please note that previous clinical trials of exposure therapy have found an average dropout rate of 21% (Hembree et al., 2003), though more recent studies of Veteran patients with PTSD have reported higher dropout rates. For example, an observational study of Veterans treated with prolonged exposure in clinical practice at a VA Medical Center reported a 34% drop out rate *when drop out was defined as completing 6 sessions of PE* (Our study requires 10 sessions). Similarly, a large RCT of women Veterans receiving 10 sessions of prolonged exposure reported a 38% drop out rate (Schnurr et al., 2007). As a point of reference, a meta-analysis of 19 medication trials for PTSD (Van Etten & Taylor, 1998) reported an average dropout rate of 32%. In this context, our dropout rate, although scientifically undesirable, may not be surprising. In addition to the challenges faced by all patients in similar studies, our patients had to contend with training exercises, PCS, ETS, finalization of medical boards, military retirements, etc. This study represents one of the first studies of treating active duty military personnel with deployment-related PTSD and we expect it to make a meaningful contribution to the scientific literature on the care of our Warriors.

KEY RESEARCH ACCOMPLISHMENTS.

Administrative and logistical matters.

- a). Personnel.
 - 1) Study staff continued enrollment, assessment, treatment and all other study-related activities.
- b) Materials, supplies and consumables.
 - 1) Supplies and materials for study requirements continue to be coordinated in support of human subject enrollment.
- c) Institutional Review Board.
 - 1) Annual Continuing review conducted by the MAMC IRB was approved 30MAY2012.

REPORTABLE OUTCOMES.

None

CONCLUSION.

None

REFERENCES.

None

APPENDICES.

None